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| EXAMINER | |
|---|---|
| LONG, SCOTT | |

| ART UNIT | PAPER NUMBER |
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| 1633 | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/544,145 | MOHAPATRA, SHYAM S. | |
| | Examiner | Art Unit | |
| | Scott D. Long | 1633 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *13 November 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-13,16-21 and 24-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13, 16-21, 24-26* is/are rejected.

7)☒ Claim(s) *26* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

*The examiner acknowledges receipt of Applicant's Remarks and Claim amendments, filed on 13 November 2007.*

### *Claim Status*

Claims 9, 14-15, and 22-23 are cancelled. Claims 1, 2, 5, 6, 10, 11, 17-21 are amended. Claims 24-26 are newly added. Claims 1-8, 10-13, 16-21 and 24-26 are under current examination.

### *Priority*

This application claims benefit as a 371 of PCT/US04/04262 (filed 02/13/2004) which claims benefit of 60/319,946 (filed 02/14/2003) and claims benefit of 60/319,956 (filed 02/19/2003). The instant application has been granted the benefit date, 02/14/2003, from the application 60/319,946.

***Response to Arguments - Claim Rejections 35 USC § 112***

*Response to Arguments – Written Description (35 USC 112, first paragraph)*

Applicant's arguments (Remarks, pages 5-6) filed 13 November 2007 have been fully considered and they are persuasive.

The applicant has essentially argued that although there is but a single species of the genus of chitosan derivatives exemplified in the specification (i.e., chitosan), the prior art and the lists of linkage sites and functional groups provided in the specification are sufficient to provide support for possession of the claimed genus. The examiner accepts that the field of chitosan-DNA complexes is fairly well developed and that a skilled artisan could take the teachings of the prior art or the instant application and extrapolate a single example which uses chitosan complexes into a variety of complexes comprising chitosan derivatives, as generally understood in the art.

Therefore, the examiner hereby withdraws the rejection of claims 1-8, 10-13, and 16-22 under 35 USC 112, first paragraph (written description).

*Response to Arguments – Scope of Enablement (35 USC 112, 1st paragraph)*

Applicant's arguments (Remarks, pages 6-9) filed 13 November 2007 have been fully considered and they are persuasive.

The applicant makes a strong case in support of the proposition that the specification is fully enabling for the scope of the instant claims, including the use of an art recognized animal model which is reasonably predictive of gene expression in mammals exhibiting asthmatic symptoms.

Therefore, the rejection of claims 1-4, 8-11 and 17 under 35 USC 112, first paragraph is hereby withdrawn.

***Response to Arguments - Claim Rejections 35 USC § 102***

Applicant's arguments (page 9) and claim amendments filed 13 November 2007, regarding rejection of claims 1, 3-5, 7, 8, 10, 12, 13, 16-18, 20 and 21 under 35 USC 102(b) as anticipated by Truong et al. (WO99/36089) have been fully considered and are persuasive.

The claim amendments incorporating "lipid" into the complexes of the instant claims are not taught by Truong et al.

Therefore, the examiner hereby withdraws the rejection of claims 1, 3-5, 7, 8, 10, 12, 13, 16-18, 20 and 21 under 35 USC 102(b) as anticipated by Truong et al.

Applicant's arguments (pages 9-10) and claim amendments filed 13 November 2007, regarding rejection of claims 1-8, 10-13, 16-21 under 35 USC 102(e) as anticipated by Ni et al. (US2002/0151009) have been fully considered but are unpersuasive.

The applicant states, "Ni merely teaches that fatty acids and chitosan are among many of the laundry list of agents that can be used in the formulation of compositions" (Remarks, page 10, parag. 1). The applicant states that Ni et al. do not teach or suggest a particle comprising chitosan and a polynucleotide and a lipid. Contrary to the applicant's assertion, the teachings of Ni et al. anticipate a composition comprising DNA, chitosan, and lipid. Ni et al. teach, "formulations and methods of administration that can be employed when the compound comprises a nucleic acid...can be selected from among those described herein below...encapsulation in liposomes" (parag.0410-0411). Ni et al. further teach formulations comprising nucleic acids and biodegradable polymers such as chitosan with combinations and mixtures of other materials (page 113, parag.1032). Ni et al. further teach "formulations comprising compositions of the invention and a biodegradable polymer may also include release rate modification agents" (page 113, col.1034). Ni et al. teach that their controlled release formulations may also include release-rate modification agents and/or pore-forming agents such as fatty acids (lipids) (page 56, parags. 0537-0538). Ni et al. clearly suggests a particle comprising (1) nucleic acids, (2) the biodegradable polymer, chitosan, and (3) the release-rate modification agent, fatty acids (also known as lipids).

Therefore, the examiner hereby maintains the rejection of claims 1-8, 10-13, 16-21 under 35 USC 102(e) as anticipated by Ni et al. for the reasons of record and the comments above.

***Response to Arguments – Double Patenting***

Applicant's arguments (page 10) and claim amendments filed 13 November 2007, regarding rejection of claims 10-13, 16-18 and 20 under obviousness double patenting over claims 1-3, 9, 10, 13, and 15-18 of copending application 11/117169 have been fully considered and are persuasive.

The claim amendments have made the rejection moot.

Therefore, the examiner hereby withdraws the rejection of the instant claims under ODP.

## NEW GROUNDS OF REJECTION

### *Claim Objections*

Claim 26 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The further limitation of claim 26 is either redundant or broader than claim 1. The examiner does not see how the limitation of claim 26 narrows claim 1.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-8, 10-13, 16-21 and 24-26 are rejected under 35 U.S.C. 102(e) as being anticipated by Ni et al (US2002/0151009, published 17 October 2002).

Claim 1 is directed to a particle comprising chitosan, or a chitosan derivative, a lipid; and a polynucleotide. Ni et al. anticipate a composition comprising DNA, chitosan, and lipid. Ni et al. teach, "formulations and methods of administration that can be employed when the compound comprises a nucleic acid...can be selected from among those described herein below...encapsulation in liposomes" (parag.0410-0411). Ni et al. further teach formulations comprising nucleic acids and biodegradable polymers such as chitosan with combinations and mixtures of other materials (page 113, parag.1032). Ni et al. further teach "formulations comprising compositions of the invention and a biodegradable polymer may also include release rate modification agents" (page 113, col.1034). Ni et al. teach that their controlled release formulations may also include release-rate modification agents and/or pore-forming agents such as fatty acids (lipids) (page 56, parags. 0537-0538). Ni et al. clearly suggests a particle comprising (1) nucleic acids, (2) the biodegradable polymer, chitosan, and (3) the release-rate modification agent, fatty acids (also known as lipids).

Claim 2 is directed to the particle of claim 1, wherein said particle is a nanoparticle. It is well established in the art that delivery of nucleic acids in particles comprising substances such as chitosan or liposomes is in the nano-scale.

Claim 3 is directed to the particle of claims 1, wherein said polynucleotide encodes a cytokine. Ni et al. teach polynucleotides of the present invention may be useful to an agent to increase cytokine production (page 67, parag. 0666). Ni et al. teach various cytokines, including interferon gamma (page 119, parag. 1081). Ni et al. also describe recombinant DNA technology involving interferon gamma (page 26, parag. 0272).

Claim 4 is directed to the particle of claim 1, wherein said polynucleotide encodes interferon gamma. Ni et al. teach interferon gamma (page 119, parag. 1081). Ni et al. also describe recombinant DNA technology involving interferon gamma (page 26, parag. 0272).

Claim 5 is directed to a composition comprising a particle and a pharmaceutically acceptable carrier, wherein said particle comprises a complex of chitosan, or a chitosan derivative, a lipid, and a polynucleotide. Ni et al. teach pharmaceutical compositions of the invention (page 43, parag. 0407).

Claim 6 is directed to the composition of claim 5, wherein said particle is a nanoparticle. It is well established in the art that delivery of nucleic acids in particles comprising substances such as chitosan or liposomes is in the nano-scale.

Claim 7 is directed to the composition of claim 5, wherein said polynucleotide encodes a cytokine. Ni et al. teach polynucleotides of the present invention may be

useful to an agent to increase cytokine production (page 67, parag. 0666). Ni et al. teach various cytokines, including interferon gamma (page 119, parag. 1081). Ni et al. also describe recombinant DNA technology involving interferon gamma (page 26, parag. 0272). Ni et al. teach pharmaceutical compositions of the invention (page 43, parag. 0407).

Claim 8 is directed to the composition of claim 5, wherein said polynucleotide encodes interferon gamma. Ni et al. teach polynucleotides of the present invention may be useful to an agent to increase cytokine production (page 67, parag. 0666). Ni et al. teach various cytokines, including interferon gamma (page 119, parag. 1081). Ni et al. also describe recombinant DNA technology involving interferon gamma (page 26, parag. 0272). Ni et al. teach pharmaceutical compositions of the invention (page 43, parag. 0407).

Claim 10 is directed to a method for delivery and expression of a polynucleotide within a mammal, said method comprising administering a particle to the mammal, wherein the particle comprises a complex of chitosan, or a chitosan derivative, a lipid, and a polynucleotide, wherein the polynucleotide is expressed in the mammal. Ni et al. teach, methods of treatment using gene therapy wherein non-replicating DNA sequences can be introduced into the cells of a mammal and provide production of the desired polypeptide for periods of up to six months," (page 124, parag.1124).

Claim 11 is directed to the method of claim 10, wherein said particle is a nanoparticle. It is well established in the art that delivery of nucleic acids in particles comprising substances such as chitosan or liposomes is in the nano-scale.

Claim 12 is directed to the method of claim 10, wherein the polynucleotide encodes a cytokine. Ni et al. teach polynucleotides of the present invention may be useful to an agent to increase cytokine production (page 67, parag. 0666). Ni et al. teach various cytokines, including interferon gamma (page 119, parag. 1081). Ni et al. also describe recombinant DNA technology involving interferon gamma (page 26, parag. 0272).

Claim 13 is directed to the method of claim 10, wherein the polynucleotide encodes interferon gamma. Ni et al. teach polynucleotides of the present invention may be useful to an agent to increase cytokine production (page 67, parag. 0666). Ni et al. teach various cytokines, including interferon gamma (page 119, parag. 1081). Ni et al. also describe recombinant DNA technology involving interferon gamma (page 26, parag. 0272).

Claim 16 is directed to the method of claim 10, wherein the particle is administered within a composition comprising a pharmaceutically acceptable carrier. Ni et al. teach pharmaceutical compositions of the invention (page 43, parag. 0407).

Claim 17 is directed to a method for enhancing interferon-gamma expression to regulate the production of cytokines secreted by T-helper type 2 (Th2) cells, said method comprising administering an effective amount of a particle to a mammal, wherein the particle comprises chitosan, or a chitosan derivative, a lipid, and a polynucleotide encoding interferon-gamma and wherein the polynucleotide is expressed, producing interferon-gamma in the mammal. Ni et al. teach polynucleotides of the present invention may be useful to an agent to increase cytokine production

(page 67, parag. 0666). Ni et al. teach various cytokines, including interferon gamma (page 119, parag. 1081). Ni et al. also describe recombinant DNA technology involving interferon gamma (page 26, parag. 0272). Ni et al. also teach "administration of polynucleotides...of the present invention...[modulate] proliferation, differentiation, or chemotaxis of T-cells" (page 59-60, parag.0580).

Claim 18 is directed to the method of claim 17, wherein the mammal is human. Ni et al. teach that their compositions could be used to treat humans (page 58, parag. 0563).

Claim 19 is directed to the method of claim 17, wherein the mammal is suffering from asthma. Ni et al. teach, "compositions of the invention may be used as agents for immunological disorders including...asthma." (page 7, parag.0086).

Claim 20 is directed to the method of claim 17, wherein the particle is administered to the respiratory tract of the mammal. Ni et al. teach aerosol administration of the compositions (page 58, parag. 0561).

Claim 21 is directed to a method for producing a particle comprising a complex of chitosan, or a chitosan derivative and a polynucleotide, said method comprising mixing the polynucleotide, the lipid, and the chitosan or chitosan derivative, to form the particle. Ni et al. teach formulations comprising nucleic acids and chitosan and combinations and mixtures of other materials (page 113, parag. 1032). Ni et al. teach creating the particles through a process of mixing (page 44, parag.0418).

Claim 24 is directed to the method of claim 10, wherein the particle is administered intranasally. Ni et al. teach intranasal administration (page 43, parag.0411).

Claim 25 is directed to the particle of claim 1, wherein the lipid is a cationic lipid or phospholipid. Ni et al. teach certain embodiments wherein the polynucleotide is complexed with cationic lipids (page 55, parag.0535).

Claim 26 is directed to the particle of claim 1, wherein the particle comprises chitosan. Ni et al. teaches particles comprising chitosan.

Accordingly, Ni et al. anticipated the instant claims.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

No claims are allowed.

***Examiner Contact Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Scott Long** whose telephone number is **571-272-9048**. The examiner can normally be reached on Monday - Friday, 9am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Joseph Woitach** can be reached on **571-272-0739**. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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*JLE*